

JUN 14 2001

K011035

DADE BEHRING

DADE BEHRING INC.
P.O. Box 6101
Newark, DE 19714

Summary of Safety and Effectiveness Information

Dade Behring Drug Calibrator

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR§807.92.

Submitter's Name: Richard M. Vaught
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: April 4, 2001

Name of Product: Dade Behring Drug Calibrator (DC22B)

FDA Classification Name: Calibrator (21CFR§862.1150)

Predicate Device: The existing Dade Behring Drug Calibrator (DC22A). This product has been used in calibrating the four (4) methods - phenobarbital, phenytoin, theophylline and digoxin on Dimension® and aca® clinical analyzers since 1986.

Device Description: The Dade Behring Drug Calibrator (DC22B) is a human serum base, liquid product containing weighed-in quantities of lithium, phenobarbital, phenytoin, theophylline and digoxin.

Intended Use: The Dade Behring Drug Calibrator (DC22B) is an *in vitro* diagnostic product intended to be used to calibrate lithium, phenobarbital, phenytoin and theophylline methods on the Dade Behring Dimension® system and to calibrate digoxin on both the Dade Behring aca® and Dimension® systems.

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Comparison to Predicate Device:

	Proposed Dade Behring Drug Calibrator (DC22B)	Dade Behring Drug Calibrator (DC22A)
Intended Use:	For calibration of the following Dimension® methods Lithium Phenobarbital Phenytoin Theophylline Digoxin*	For calibration of the following Dimension® methods ----- Phenobarbital Phenytoin Theophylline Digoxin*
<hr/>		
*For both Dimension® and aca® systems		
Form:	weighed-in; human serum base	weighed-in; human serum base
Levels:	5 levels; two vials/level; 3mL/vial	5 levels; two vials/level 3mL/vial

Comments on Substantial Equivalence:

The proposed Dade Behring Drug Calibrator (DC22B) and the existing Dade Behring Drug Calibrator (DC22A) are *in vitro* diagnostic products intended as calibrators for both the Dade Behring Dimension® and aca® clinical analyzer systems. Both calibrator products contain weighed in quantities of phenobarbital, phenytoin, theophylline and digoxin.

The existing product (DC22A) was revised by including weighed-in quantities of lithium carbonate to permit the additional calibration of the Dimension® Lithium (LI) method.

Conclusion:

The multi-analyte, five level, human serum base Dimension® Drug Calibrator (DC22B) is substantially equivalent to the existing Dimension® Drug Calibrator (DC22A) product based on its design and intended use.



Richard M. Vaught
Regulatory Affairs and Compliance Manager
Date: April 4, 2001

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 14 2001

Mr. Richard M. Vaught
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
Gasglow Business Community
Bldg. 500, M.S. 514
P.O. Box 6101
Newark, DE 19714-6101

Re: 510(k) Number: K011035
Trade/Device Name: Dade Behring Drug Calibrator
Regulation Number: 862.1150
Regulatory Class: II
Product Code: JIX
Dated: April 4, 2001
Received: April 5, 2001

Dear Mr. Vaught:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script that reads "Steven Gutman".

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

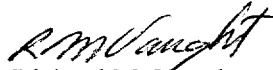
510(k) NUMBER: K011035

Device Name:

Dade Behring Drug Calibrator

Indications for Use:

The Dade Behring Drug Calibrator is a device intended for medical purposes to establish points of reference that are used in determination of values in the measurement of substances in human specimens.



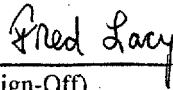
Richard M. Vaught

Regulatory Affairs and Compliance Manager

April 4, 2001

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K011035

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-the-counter Use ☐

(Optional format 1-2-96)

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